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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/051,766      | 01/17/2002  | Richard J. Fitzpatrick | 1932.1110-001       | 5568             |

21005 7590 07/01/2003

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

[REDACTED] EXAMINER

FUBARA, BLESSING M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615     | 61           |

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                |                    |
|--|--------------------------------|--------------------|
| <b>Office Action Summary</b>   | Application No.                | FITZPATRICK ET AL. |
|  | 10/051,766                     | Art Unit           |
|  | Examiner<br>Blessing M. Fubara | 1615               |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>   |                                |                    |
| <b>Period for Reply</b>  |                                |                    |
| <b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>   |                                |                    |
| <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> |                                |                    |
| <b>Status</b>  |                                |                    |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>14 April 2003</u> .  |                                |                    |
| 2a) <input type="checkbox"/> This action is FINAL.                    2b) <input checked="" type="checkbox"/> This action is non-final.  |                                |                    |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                                |                    |
| <b>Disposition of Claims</b>   |                                |                    |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-32</u> is/are pending in the application.   |                                |                    |
| 4a) Of the above claim(s) <u>9,11-19 and 25-32</u> is/are withdrawn from consideration.  |                                |                    |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed.   |                                |                    |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-8,10 and 20-24</u> is/are rejected.   |                                |                    |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to.   |                                |                    |
| 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.   |                                |                    |
| <b>Application Papers</b>  |                                |                    |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner.  |                                |                    |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                                |                    |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br>If approved, corrected drawings are required in reply to this Office action.  |                                |                    |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.   |                                |                    |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>   |                                |                    |
| 13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).<br>a) <input type="checkbox"/> All    b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:<br>1. <input type="checkbox"/> Certified copies of the priority documents have been received.<br>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.<br>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).<br>* See the attached detailed Office action for a list of the certified copies not received.  |                                |                    |
| 14) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).<br>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.   |                                |                    |
| 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                                |                    |
| <b>Attachment(s)</b>   |                                |                    |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  |                                |                    |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   |                                |                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6,8,10</u> .  |                                |                    |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____   |                                |                    |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |                                |                    |
| 6) <input type="checkbox"/> Other: _____   |                                |                    |

## **DETAILED ACTION**

Examiner acknowledges receipt of, declaration, fee, power of attorney and preliminary amendment filed 05/07/02, and IDS filed 10/31/02, supplemental IDS filed 12/27/02, 03/14/03 and 04/15/03 and election and amendment filed 04/14/03.

### ***Information Disclosure Statement***

The information disclosure statement filed 10/31/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The non-US references cited in the Form PTO-1449 are not available to the examiner to review. Examiner respectfully requests applicants to submit the non-US references.

### ***Election/Restrictions***

Examiner thanks applicants for electing the ionene polymer depicted in claim 24 and oral mucositis that is a side effect of radiation therapy. Applicants also identified claims 1-8 and 10-32 as the claims readable on the elected species. However, the repeating units of the ionene polymer recited/depicted in claims 11-19 and 25-32 are not the same as the elected repeating unit of the ionene polymer of claim 24. Thus the claims readable on the elected species are 1-8, 10 and 20-24 and accordingly, claims 1-8, 10 and 20-24 are examined on the merits.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of mucositis, reduction in severity and reduction in size of mucositis, does not reasonably provide enablement for prophylaxis/prevention of mucositis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. There is no established exemplification on how mucositis is prevented.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to a method for treating mucositis where the method comprises administering an effective amount of an ionene polymer.

2) State of the prior art.

The prior art does not indicate that ionene polymers are administered to prevent mucositis or a long standing and accepted evidence and data showing that mucositis is preventable by administering a composition to a subject in need thereof.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high only in the area of treatment, inhibition, reduction in severity and reduction in size of mucositis.

4) Level of predictability in the art.

The art does not present data showing how mucositis can be treated prophylactically or prevented. Since there is no showing through standing experimentation and data, there would be little predictability in performing the claimed method where ionene polymer is administered to prevent mucositis or prophylactically treat mucositis.

5) Amount of direction and guidance provided by the inventor.

The guidance provided by applicants is in the area of treatment and applicants no guidance provided where the administration of ionene polymer prevents mucositis.

6) Existence of working examples.

Applicants presented no working examples where the ionene polymer is administered to prevent mucositis.

7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain compounds of formula (II) as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation; see *In re Armbruster* 185 USPQ 152 CCPA 1975.

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 10, and 20-24 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-38, 42-44 and 48-50 of copending Application No. 10/051,765, which is now a published application number US 2003/0031644. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are obvious over the claims of the co-pending application. The method of claim 1 differs from the method of claim 42-44 in that in the application treats mucositis or stomatitis whereas the method of claims 42-44 treats microbial infection. However, the portion of co-pending application supports treating mucositis with polyionene polymers (paragraph 130).

Therefore, it would have been obvious to administer the polyionene copolymer to a subject in need thereof. One having ordinary skill in the art would have been motivated

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to administer the polyionene polymer to a subject in need thereof with the expectation of treating mucositis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

June 27, 2003